

Notice of Allowability

Application No.

09/402,282

Examiner

Bo Peng

Applicant(s)

TEDDER ET AL.

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 8/21/07 & 10/25/07.
2. ☒ The allowed claim(s) is/are 98-103.
3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
- * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|--|---|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date _____ |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____ |

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1. The amendment filed on August 19, and the supplemental amendment filed on October 25, 2007, are acknowledged. Claims 1-7, 11, 19, 24, 25, 2732-37, 39, 41, 44-80, 96 and 97 are canceled. Claims 8, 9, 17, 18, 20-23, 26, 28-31, 38, 40, 42, 43 and 81-95 were withdrawn as non-elected. Claims 10 and 12-16 are considered.
2. The amendment to the specification and copies of deposit certification of the claimed hybridoma cells in the ECACC, submitted on October 25, 2007, are acknowledged. Attorney's statement that the specific hybridoma cells as recited in the claims will be irrevocably and without restriction or condition released to the public upon the issuance of a U.S. patent is presented in the Remarks filed on November 17, 2006. (p. 16 and 17).

35 USC § 112, first paragraph

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. The rejection of Claims 10 and 12-16 under 35 U.S.C. 112, first paragraph for failing to comply with written description is **withdrawn** in view of the amendment.

Claim Rejections - 35 USC § 102

5. The following is a quotation from the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. The rejection of Claim 12 under 35 U.S.C. 102(b), as being anticipated by Mangold CM et al. (1995, Virology, Vol. 211, p.535-543), is **withdrawn** in view of the amendment.

Claim Rejections - 35 USC § 102/103

7. The rejection of Claim 12 under 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under 35 U.S.C. § 103 as obvious over Waters et al. (WO 94/21812), is **withdrawn** in view of the amendment.

EXAMINER'S AMENDMENT

8. An Examiner's Amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

9. Authorization for this Examiner's Amendment was given in a telephone interview with Attorney Cheryl Becker on October 25, 2007.

10. Cancel Claims 1-6, 8-10, 12-18, 20-23, 26, 28-31, 38, 40, 42, 43 and 59-97.

11. Add new Claims 98-103 set forth below:

Claim 98: A monoclonal which binds to an epitope of two or more HBsAg variants, wherein said epitope comprises the mutations selected from the group consisting of:

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(a) Met to Ile at amino acid 133, Phe to His at amino acid 134, and Asp to Val at amino acid 144 of NP HBsAg;

(b) Met to Ile at amino acid 133, Phe to Asn at amino acid 134, Pro to Ser at amino acid 142, Ser to Leu at amino acid 143, and Gly to Lys at amino acid 145 of MAM HBsAg; and

(c) Ser to Met at amino acid 143 of SP HBsAg.

Claim 99: A monoclonal antibody as claimed in claim 98 that is an IgG, IgM or IgA immunoglobulin.

Claim 100: Monoclonal antibody P2D3 as produced by the hybridoma designated P2D3 and deposited at the ECACC under accession number ECACC 97042331.

Claim 101: Monoclonal antibody M3A10 as produced by the hybridoma designated M3A10 and deposited at the ECACC under accession number ECACC 97042330.

Claim 102: Monoclonal antibody M4F5 as produced by the hybridoma designated M4F5 and deposited at the ECACC under accession number ECACC 97042519.

Claim 103: A monoclonal antibody as claimed in claim 98, in a humanized form.

Conclusion

12. Claims 98-103 are pending and allowed.

13. Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue


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fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bo Peng, Ph.D. whose telephone number is 571-272-5542. The examiner can normally be reached on M-F, 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell, Ph.D. can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.


Bo Peng, Ph.D.
October 26, 2007



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